



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 1, 1999

MEMORANDUM

SUBJECT: REVISED Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) Document.
DP Barcode No.: D256875
Chemical No.: 057501
Reregistration Case No.: 0155

FROM: Bonnie Cropp-Kohlligian, Environmental Scientist
Reregistration Branch II
Health Effects Division [7509C]

THROUGH: Alan P. Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division [7509C]

TO: Richard Griffin, Risk Assessor
Reregistration Branch II
Health Effects Division [7509C]

A Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) Document was completed 5/27/98. Attached is the most recent revision of this RED Chapter hereafter referred to as the Residue Chemistry Chapter for the Parathion RED Document (REV 9/99).

Subsequent to the completion of the Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) Document (5/27/98), the Agency issued a Preliminary Human Health Risk Assessment entitled, "Ethyl Parathion. Dietary and Occupational Risk Assessments" (completed 10/28/98). In response to the Agency's Preliminary Human Health Risk Assessment of Parathion (completed 10/28/98), Jellinek, Schwartz & Connolly, Inc. submitted extensive comments under separate covers (dated 12/4/98 and 3/16/99) to the Agency on behalf of Cheminova Agro A/S. In their initial response dated 12/4/98, the registrant clarified the

maximum food/feed use patterns and restrictions of parathion which they wish to support under reregistration. They also committed to generate additional residue chemistry data in support of the reregistration of parathion. In their later response dated 3/16/99, the registrant proposed further changes to the maximum use patterns of parathion, primarily to reduce the number of applications/season to be consistent with what they believe are more typical use patterns. [Note: While HED has no objections to further reductions to the number of applications/season of parathion on food/feed crops as proposed by the registrant in their 3/16/99 response to the Agency's Preliminary Human Health Risk Assessment (10/28/98), the available residue chemistry data are not reflective of fewer applications/season of parathion than those proposed by the registrant in their earlier (12/4/98) response to the Agency's Preliminary Human Health Risk Assessment (10/28/98).]

Subsequent to the completion of the Agency's Preliminary Human Health Risk Assessment (10/28/98), Cheminova Agro A/S submitted LD₅₀ data for 4-acetamidoparaoxon which were considered, along with new livestock feeding studies, by the HED Metabolism Assessment Review Committee. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian and N. Paquette dated 9/1/99) has concluded that the weight of the available evidence is sufficient to demonstrate that 4-acetamidoparaoxon residues incurred in animal commodities from exposure of livestock to residues of parathion in/on feed items do not need to be included in the dietary risk assessment for parathion.

The information contained in this document outlines the current residue chemistry science assessment with respect to the reregistration of parathion and takes into account the responses of Cheminova (dated 12/4/98 and 3/16/99) to the Agency's Preliminary Human Health Risk Assessment of Parathion (completed 10/28/98). It also takes into account the following new residue chemistry data submitted by the registrant, in support of the reregistration of parathion, which are under review: (i) Independent Laboratory Validation (ILV) data for residues of parathion, paraoxon, and 4-acetamidoparaoxon in kidney and milk (MRID 44547401), (ii) storage stability data on field corn grain, meal, grits, flour, starch, and refined oil (MRID 44559601) and test sample storage intervals/conditions information from magnitude of the residue studies (MRID 44640501), (iii) barley grain, hay, and straw field trial data (MRID 44602201), (iv) magnitude of the residue data on aspirated grain fractions (AGF) derived from wheat grain (MRID 44590201) and sorghum grain (MRID 44591301), (v) cotton gin trash magnitude of the residue data (MRID 44594901), and (vi) confined rotational crop data (no MRID; ABC Laboratories Report 36837-3; cover letter from Jellinek, Swartz & Connolly, Inc. dated 11/12/91).

Note to SRRD: As you are aware, due to the Agency's concern about worker exposure to parathion, the Agency and registrants of parathion products reached an agreement (*Federal Register Notices Vol. 56, No. 240 dated 11/13/91; and Vol. 57, No. 19 dated 1/29/92 and No. 34 dated 2/20/92*) under which uses of parathion would be allowed only on the following food/feed crops: alfalfa, barley, canola, corn, cotton, sorghum, soybean, sunflower, and wheat. In their responses to the Agency's Preliminary Human Risk Assessment of Parathion, the registrant (Cheminova) has made it clear to the Agency that they will only support the food/feed uses of

parathion specified under our agreement. At this time, no other party has committed to support any other use of parathion. Hence, the Residue Chemistry Science Assessments and Tolerance Reassessment Summary only include recommendations for commodities of the food/feed crops specified under the agreement referred to above. If the Agency determines that other uses of parathion and/or tolerances for residues of parathion must be retained, additional residue chemistry data may be required to support the reregistration of parathion.

Attachment: Residue Chemistry Chapter for the Parathion RED Document (REV 9/99)

cc w/attachment: BLCKohlligian (RRB2), Dennis Deziel (SRRD), Parathion Reg. Std. File, Parathion SF, RF.

7509C:RRB2:BLCKohlligian:CM#2:Rm 712N:703-305-7462: 8/25/99.

Residue Chemistry Chapter for the Parathion RED Document (REV 9/99)

INTRODUCTION

Parathion [*O,O*-diethyl *O-p*-nitrophenyl thiophosphate] is an insecticide registered for use on alfalfa, barley, corn, cotton, rape seed, sorghum, soybean, sunflower, and wheat. Parathion is manufactured by Cheminova Agro A/S, the basic producer, under the trade name Ethyl Parathion. Parathion formulations registered by the basic producer for use on food/feed crops include three emulsifiable concentrate (EC) formulations. These products may be applied as broadcast foliar applications using only aerial equipment. Multiple Active Ingredient (MAI) formulations of parathion are registered in combination with methyl parathion.

REGULATORY BACKGROUND

Due to the Agency's concern about worker exposure to parathion, the Agency and registrants of parathion products reached an agreement (*Federal Register Notices Vol. 56, No. 240 dated 11/13/91; and Vol. 57, No. 19 dated 1/29/92 and No. 34 dated 2/20/92*) under which uses of parathion would be allowed only on the following food/feed crops: alfalfa, barley, canola, corn, cotton, sorghum, soybean, sunflower, and wheat. This agreement also required that label directions for parathion products be amended to allow only aerial applications by certified commercial applicators and only mechanical harvesting of treated crops; hand-harvesting of parathion-treated crops was to be prohibited.

Parathion is a List A reregistration chemical and was the subject of a Registration Standard (4/8/85) and its associated Guidance Document (12/86), a Reregistration Standard Update (8/17/93), a Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) Document (5/27/98), and a Preliminary Human Health Risk Assessment (10/28/98). In response to the Agency's Preliminary Human Health Risk Assessment of Parathion (10/28/98), Jellinek, Schwartz & Connolly, Inc. submitted extensive comments under separate covers (dated 12/4/98 and 3/16/99) to the Agency on behalf of Cheminova Agro A/S. In their initial response dated 12/4/98, the registrant clarified the maximum food/feed use patterns and restrictions of parathion which they wish to support under reregistration. They also committed to generate additional residue chemistry data in support of the reregistration of parathion. In their later response dated 3/16/99, the registrant proposed further changes to the maximum use patterns of parathion, primarily to reduce the number of applications/season of parathion on crops to be consistent with what they believe are more typical use patterns.

On 3/11/98 the HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohliligian dated 5/21/98) met to discuss the available parathion plant and animal metabolism data and concluded that parathion residues of concern in plant commodities include parathion, its metabolite paraoxon [*O,O*-diethyl-*O-p*-nitrophenyl phosphate], and *p*-nitrophenol and that parathion residues of concern in animal commodities include parathion, paraoxon, *p*-nitrophenol, and 4-acetamidoparaoxon. The tolerance expression for plant and animal commodities should be based on parathion only. Parathion residues of concern to be included in the risk assessment for plant commodities with regard to cholinesterase inhibition should include parathion and paraoxon. Parathion residues of concern to be included in the risk assessment for animal commodities with regard to cholinesterase inhibition should include parathion, paraoxon, and 4-acetamidoparaoxon. Residues of *p*-nitrophenol resulting from the use of parathion do not have to be included in the tolerance expression or considered in the aggregate risk assessment for parathion with regard to cholinesterase inhibition, but may be considered in conjunction with a future cumulative risk assessment for *p*-nitrophenol based on its own toxicological endpoints (rather than cholinesterase).

At that same meeting, the HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohliligian dated 5/21/98) further concluded that if the registrant could demonstrate that 4-acetamidoparaoxon is much less toxic than parathion by providing evidence that the LD₅₀ for 4-acetamidoparaoxon is more than 200 mg/kg, then 4-acetamidoparaoxon residues incurred in animal commodities would not need to be included in the dietary risk assessment for parathion. Subsequently, the registrant (Cheminova) submitted LD₅₀ data for 4-acetamidoparaoxon and animal magnitude of the residue data. The HED Metabolism Assessment Review Committee reconvened on 8/24/99 to consider these new data and concluded (memo by B. Cropp-Kohliligian and N. Paquette dated 9/1/99) that the weight of the available evidence is sufficient to demonstrate that 4-acetamidoparaoxon residues incurred in animal commodities from exposure of livestock to residues of parathion in/on feed items do not need to be included in the dietary risk assessment for parathion with respect to cholinesterase inhibition.

The information contained in this document outlines the current residue chemistry science assessment with respect to the reregistration of parathion and takes into account the responses of Cheminova (12/4/98 and 3/16/99) to the Agency's Preliminary Human Health Risk Assessment of Parathion (10/28/98). It also takes into account the following new residue chemistry data submitted by the registrant, in support of the reregistration of parathion, which are under review: (I) Independent Laboratory Validation (ILV) data for residues of parathion, paraoxon, and 4-acetamidoparaoxon in kidney and milk (MRID 44547401), (ii) storage stability data on field corn grain, meal, grits, flour, starch, and refined oil (MRID 44559601) and test sample storage intervals/conditions information from magnitude of the residue studies (MRID 44640501), (iii) barley grain, hay, and straw field trial data (MRID 44602201), (iv) magnitude of the residue data on aspirated grain fractions (AGF) derived from wheat grain (MRID 44590201) and sorghum grain (MRID 44591301), (v) cotton gin trash magnitude of the residue data (MRID 44594901), and (vi) confined rotational crop data (no MRID; ABC Laboratories Report 36837-3; cover letter from Jellinek, Swartz & Connolly, Inc. dated 11/12/91).

Tolerances for residues of parathion or its methyl homolog (methyl parathion) in/on raw agricultural commodities (RACs) have been established under 40 CFR §180.121(a) and §180.319. No tolerances for residues of parathion have been established for animal commodities or processed food/feed commodities.

The chemical names and structures of parathion and paraoxon are depicted below in Figure A.

Figure A.

Common Name/Chemical Name	Chemical Structure
Parathion <i>O,O</i> -diethyl- <i>O</i> - <i>p</i> -nitrophenyl thiophosphate	
Paraoxon <i>O,O</i> -diethyl- <i>O</i> - <i>p</i> -nitrophenyl phosphate	

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 6/17/99 indicates that there are three parathion end-use products (EPs) with uses on food/feed crops registered to Cheminova, Inc. (hereafter referred to as Cheminova). These EPs are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
67760-37	12/96	4 lb/gal EC	PARATHION 4 EC
67760-38	12/96	8 lb/gal EC	PARATHION 8 EC
67760-39 ^a	12/96	6 lb/gal EC	ETHYL-METHYL PARATHION 6-3 EC

^a This product is a multiple active ingredient (MAI) formulation that also includes methyl parathion at 3 lb ai/gal in addition to the 6 lb ai/gal of parathion.

In accordance with an agreement between the Agency and the registrants of parathion products, uses of parathion are limited to the following food/feed crops: alfalfa, barley, canola, corn, cotton, sorghum, soybean, sunflower, and wheat.

Cheminova has submitted the majority of the residue chemistry data in support of the reregistration of parathion. The food/feed use sites, maximum use patterns, and restrictions of parathion which they wish to support, according to their initial response (12/4/98) to the Agency's Preliminary Human Health Risk Assessment of Parathion (10/28/98), are consistent with the food/feed use sites, maximum use patterns, and restrictions prescribed by the Agency, herein, with the exceptions of the number of applications/season for use of parathion on grain sorghum and wheat.

The use patterns for parathion as prescribed by the Agency, herein, are based primarily on the use patterns supported by the available residue chemistry data and secondarily on the use patterns which the registrant (Cheminova) wishes to support according to their initial response (12/4/98) to the Agency's Preliminary Human Health Risk Assessment of Parathion (10/28/98). [Note: While there are no objections to further reductions to the number of applications/season of parathion on food/feed crops as proposed by the registrant in their later response (3/16/99) to the Agency's Preliminary Human Health Risk Assessment of Parathion (10/28/98), the available residue chemistry data are not reflective of fewer applications/season than those prescribed by the Agency and, therefore, tolerance levels cannot be reassessed based on fewer applications/season than those prescribed by the Agency.] A summary of the Agency's prescribed food/feed use sites, maximum use patterns, and restrictions are presented in Table A.

A tabular summary of the residue chemistry science assessments for reregistration of parathion is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of

parathion food/feed uses are predicated on the use sites, maximum use patterns, and restrictions of parathion prescribed by the Agency and summarized in Table A. When end-use product DCIs are developed (e.g., at issuance of the RED), the Registration Division (RD) should require that all end-use product labels be amended such that they are consistent with the food/feed use sites, maximum use patterns, and restrictions specified in Table A.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on cotton, potato, and wheat metabolism studies. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) concluded that based on available plant metabolism data, parathion residues of concern in/on plant commodities are parathion, paraoxon, and *p*-nitrophenol. Parathion residues of concern to be included in the risk assessment for plant commodities based on cholinesterase inhibition should include parathion and paraoxon. The tolerance expression should be based on parathion only since detectable residues of paraoxon have not been found in/on commodities tested by FDA monitoring. Residues of *p*-nitrophenol resulting from the use of parathion do not have to be included in the tolerance expression or considered in the aggregate risk assessment for parathion with respect to cholinesterase inhibition, but may be considered in conjunction with a future cumulative risk assessment for *p*-nitrophenol based on its own toxicological endpoints (rather than cholinesterase inhibition). Residues of parathion, paraoxon, and *p*-nitrophenol should be determined in/on plant samples collected from future plant magnitude of the residue studies.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based on acceptable ruminant and poultry metabolism studies. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98 and memo by B. Cropp-Kohlligian and N. Paquette dated 9/1/99) concluded that, as with plants, based on available animal metabolism data, animal magnitude of the residue data, and 4-acetamidoparaoxon LD₅₀ data, parathion residues of concern in animal commodities are parathion, paraoxon, and *p*-nitrophenol. Parathion residues of concern to be included in the risk assessment for animal commodities based on cholinesterase inhibition should include parathion and paraoxon. The tolerance expression should be based on parathion only. Residues of *p*-nitrophenol do not have to be included in the tolerance expression or considered in the aggregate risk assessment for parathion but may be considered in conjunction with a future cumulative risk assessment for *p*-nitrophenol based on its own toxicological endpoints (rather than cholinesterase inhibition).

OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of parathion as currently defined. The Pesticide Analytical Manual (PAM) Vol. II lists Methods I(a) and I(b) (PAM, Vol. I multiresidue methods for organophosphates) and I© and I(d) for parathion.

The registrant has proposed a new enforcement method for plant commodities, which detects parathion and the metabolites paraoxon and *p*-nitrophenol. This method was described in the Parathion Update as the “acidic-extraction” method. In brief, residues in/on non-oily plant matrices are extracted by refluxing in acetone:0.1 N HCl or methanol:0.1 N HCl (80:20; v:v) for 1 hour, cooled, and filtered. Residues are then concentrated, partitioned into ethyl acetate, filtered, and reconcentrated. Residues in/on oily plant matrices are extracted with methanol:0.1 N HCl (80:20; v:v), concentrated, diluted with acetonitrile, and partitioned with hexane. Residues remaining in the acetonitrile extract are then concentrated, partitioned into ethyl acetate, dried over sodium sulfate, and reconcentrated. Residues of parathion and paraoxon in the resulting ethyl acetate fractions are then determined by GC/flame photometric detection (FPD) in the phosphorus mode. The limits of quantitation are 0.04 ppm for parathion and 0.05 ppm for paraoxon.

The proposed enforcement method for plants also includes procedures for determining *p*-nitrophenol. For the analysis of *p*-nitrophenol, residues in the ethyl acetate extract are concentrated, diluted with hexane, and cleaned-up on a Florisil column eluted with ethyl ether:hexane:methanol:acetic acid (49.5:49.4:1.0:0.1; v:v). Residues of *p*-nitrophenol are then concentrated to dryness, diluted with acetonitrile:0.1% acetic acid in water (45:55; v:v), and determined by HPLC analysis with UV detection (315 nm). The limit of quantitation for *p*-nitrophenol is 0.02 ppm.

The above methods have been successfully validated using samples of representative plant commodities by both an independent laboratory and by the Agency (D. McNeilly, 11/3/93). The proposed method has also been successfully radiovalidated using samples from plant metabolism studies.

Residue data on raw agricultural commodities (RACs) and processed commodities of plants have been collected using the above GC/FPD and HPLC methods with only minor modifications involving changes in solvents and cleanup procedures.

The registrant (Cheminova) has proposed GC/FPD enforcement methods (Leoni Methods II, IIa, and III) for residues in animal commodities; these methods have already been successfully radiovalidated using samples from the goat and hen metabolism studies (B. Cropp-Kohlligian, 3/12/97). Residue data on meat, milk, poultry, and egg have been collected using these methods. The limits of quantitation for each analyte in tissues is 10 ppb (or 0.01 ppm); the limits of quantitation for each analyte in egg and milk is 1 ppb (or 0.001 ppm). A brief description of the extraction procedures for each method follows.

Leoni Method II: Residues in eggs and whole milk are extracted with acetone, filtered, partitioned into dichloromethane (DCM), and dried with sodium sulfate (3 times). The residues in the combined organic layers are concentrated to dryness, redissolved in acetonitrile (ACN), and eluted with ACN through a column packed with diatomaceous earth. Residues in egg samples are further purified on a C₁₈ SPE column also eluted with ACN.

Leoni Method IIa: Residues in liver, kidney and muscle are extracted and concentrated as described above in Leoni Method II. The residues are taken up in benzene, cleaned-up on a carbon/Celite 545 (1:4, w:w) column with ACN/benzene (1:1, v:v), concentrated, and redissolved in ACN. The residues are then purified on a C₁₈ SPE column, evaporated to dryness, and redissolved in benzene.

Leoni Method III: Residues in milk fat and fat are hydrated in water, and extracted and concentrated as described above in Leoni Method II, using ACN instead of acetone as the extraction solvent. The residues are redissolved with hexane, cleaned-up on a column packed with diatomaceous earth, eluted with ACN, and evaporated to dryness. The residues are taken up in benzene.

The registrant (Cheminova) has submitted Independent Laboratory Validation (ILV) data (MRID 44547401) for the determination of residues of parathion, paraoxon, and 4-acetamidoparaoxon in kidney and milk which are under review. Pending acceptance of these data to satisfy guideline requirements, no additional plant and animal residue analytical methods data are required of the registrant to support the reregistration of parathion. Since tolerances for residues of parathion in/on egg, poultry muscle, poultry fat, and poultry liver are needed, a method validation study will be conducted by the Agency, as the Agency deems appropriate, determining residues of parathion and possibly residues of paraoxon and 4-acetamidoparaoxon in egg and poultry tissues (at the limit of quantitation for each analyte; 0.001 ppm and 0.01 ppm, respectively).

OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that parathion is completely recovered using FDA Multiresidue Protocols D and E (PAM I Sections 232.4, 211.1, and 212.1). Paraoxon is completely recovered using FDA Protocol D (PAM I Section 232.4), but is not recovered using Protocol E (PAM I Sections 211.1 and 212.1).

OPPTS GLN 860.1380: Storage Stability Data

For purposes of reregistration, the requirements for supporting storage stability data are satisfied for all acceptable residue studies.

The available storage stability data for plant commodities indicate that residues of parathion and paraoxon are both stable at -20 C for up to 24 months in/on almonds, apples, beans (dry), clover, corn grain, cottonseeds, oranges, peppers, plums, spinach, strawberries, and sunflower seeds, and

for up to 45.5 months in/on corn forage and fodder. Parathion is also stable in/on succulent beans stored at -20 C for up to 24 month; however, paraoxon was only stable for up to 6 months at -20 C and declined by ~30% after 24 months of storage. Parathion is also stable at -5 C in canola seed, oil, and processing waste for up to 14 months, and in canola meal for up to 6 months; residues of parathion in meal declined by ~25% after 14 months at -5 C. Residues of paraoxon are stable at -5 C in canola seed, oil, processing waste, and meal for up to 6 months, but declined by 20-35% in these matrices after 14 months of storage.

The available storage stability data for animal commodities indicate that residues of parathion, paraoxon, and 4-acetamidoparaoxon are stable at <0 C in egg for up to 47 days, in muscle and fat for approximately 40 days, and in milk for up to 64 days. Residues of parathion and 4-acetamidoparaoxon are relatively stable at <0 C in kidney for up to 41 days; however, residues of paraoxon appear to degrade rapidly and are not recovered after approximately 40 days. Residues of parathion and 4-acetamidoparaoxon are relatively unstable at <0 C in liver declining by as much as 80% and 92%, respectively, after 67 days. As with kidney, residues of paraoxon appear to degrade rapidly in liver, and are not recovered after approximately 40 days.

The registrant (Cheminova) has submitted new storage stability data on field corn grain, meal, grits, flour, starch, and refined oil (MRID 44559601) and test sample storage intervals/conditions information from magnitude of the residue studies (MRID 44640501) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the tolerance reassessment recommendations made herein or dietary exposure estimates used in the dietary risk assessment for parathion.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

Residue chemistry data depicting parathion residues of concern are required for the following food/feed crops which the Agency understands are being supported under the reregistration process: alfalfa (grown for forage and hay only), barley, canola (oilseed crop only), corn (field, pop, and sweet), cotton, grain sorghum, soybean, sunflower, and wheat. Provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, maximum use patterns, and restrictions as specified in Table A, reregistration requirements for magnitude of the residue data in/on plants are fulfilled for the following crops: canola, field corn, sweet corn, soybean, and sunflower. Likewise, reregistration requirements for magnitude of the residue data in/on plants are fulfilled for the following crop commodities: wheat grain, wheat forage, and wheat straw. The available field corn residue chemistry data will be translated to support the use of parathion on pop corn.

In support of the reregistration of the EC formulations of parathion the registrant (Cheminova) has submitted the following new residue chemistry data: (i) barley grain, hay, and straw magnitude of the residue data (MRID 44602201), (ii) magnitude of the residue data on aspirated grain fractions (AGF) derived from wheat grain (MRID 44590201) and sorghum grain (MRID 44591301), and (iii) cotton gin trash magnitude of the residue data (MRID 44594901). These data are under review. Pending acceptance of these data to fulfill guideline requirements and

provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, maximum use patterns, and restrictions as specified in Table A, no additional magnitude of the residue data are required to support the reregistration of parathion on the following crops: barley, cotton, and grain sorghum.

For the purposes of reregistration, additional magnitude of the residue data are required to support the use of the EC formulations of parathion on the following crop commodities: alfalfa forage, alfalfa hay, and wheat hay. No alfalfa forage, alfalfa hay, and wheat hay magnitude of the residue data reflecting the maximum use patterns of parathion on alfalfa and wheat are available.

Data are required depicting parathion residues of concern in/on alfalfa forage and hay harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.50 lb ai/A/application with a 7-day RTI. The registrant should refer to OPPTS GLN 860.1500 for information on location and number of field trials required. Since it is unlikely that the currently established tolerances for residues of parathion in/on alfalfa forage and alfalfa hay are adequate, these required data are considered critical to tolerance reassessment. The registrant (Cheminova) has committed to generate the required data.

Additional data are required depicting parathion residues of concern in/on wheat hay harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.50 lb ai/A/application with a 14-day RTI. [Note: It is inappropriate to translate available barley hay data to wheat hay since the available barley hay data reflect a significantly higher use rate of parathion than that which is being support for the use of parathion on wheat.] However, the Agency will limit the number of field trials needed to three bridging wheat field trials, one each in Regions 5, 7, and 8 conducted at the 1x rate in which all RACs of wheat are collected. The registrant (Cheminova) has not committed to generate these data.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

In support of the reregistration of parathion, processing data are required on the following food/feed crop commodities: barley grain, canola seed, field corn grain, cottonseed, soybeans, sunflower seed, and wheat grain. Reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for canola seed, field corn grain, cottonseed, sunflower seed, and wheat. The available wheat grain processing data will be translated to the processed commodities of barley grain. The available cottonseed, grain sorghum (not required), and sunflower seed processing studies indicate that residues of parathion do not concentrate in any cottonseed (meal, hulls, or oil), grain sorghum (flour, grits or starch) and sunflower seed (meal and oil) processed fraction.

For canola seed, residues of parathion do not concentrate in canola meal, but concentrate by 1.5x in refined canola oil. Based upon this concentration factor (1.5x) and the Highest Average Field Trial (HAFT) value (0.13 ppm) for residues of parathion in/on canola seed and considering the recommended reassessed tolerance for residues of parathion in/on canola seed (0.2 ppm), a

separate tolerance for residues of parathion in canola oil is not required.

For field corn grain, residues of parathion do not concentrate in corn meal, flour, grits or starch, but concentrate on average by ~3x in refined corn oil by the wet milling process. Based upon this concentration factor (3x) and the current HAFT value for residues of parathion in/on field corn grain (0.0877 ppm), a 0.3 ppm tolerance for residues of parathion in refined corn oil should be established.

For wheat grain, residues of parathion do not concentrate in wheat flour, middlings, or shorts, but concentrate by 4.6x in wheat bran. The concentration factor for wheat bran (4.6x) will also be translated to barley bran. Based upon the HAFT values for residues of parathion in/on wheat grain (0.52 ppm) and barley grain (4.3 ppm) and the concentration factor for wheat bran (4.6x), tolerances of 3 ppm and 20 ppm should be established for residues of parathion in wheat bran and barley bran, respectively.

Soybeans processing data are required depicting the potential for concentration of parathion residues of concern in soybean hulls, meal and refined oil processed from seeds bearing detectable parathion residues. If no detectable residues are found in/on soybeans harvested from plants treated at a 5x exaggerated rate, a processing study will not be required.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The available ruminant and poultry feeding studies are deemed adequate to support the reregistration of parathion. No additional meat, milk, poultry, and egg magnitude of the residue data are required.

Maximum Theoretical Dietary Burden Calculations: Based on the available plant magnitude of the residue data depicting residues of parathion in/on animal feed items, the potential contributions to the maximum theoretical dietary burdens of livestock from feed items of canola, soybean, and sunflower treated with parathion are expected to be very insignificant. Furthermore, considering the most recent Qualitative Usage Analysis (QUA) report for Parathion (BEAD report by I. Yusuf and T. Kiely dated 1/22/99) which predicts an extremely low percent of alfalfa, barley, corn, cotton, sorghum, and wheat will be treated with parathion (maximum of ≤ 1.5 percent for each of these crops), it is highly unlikely that livestock will be exposed to multiple feed items treated with parathion at the maximum use rates and improbable that exposure from multiple feed items treated with parathion would exceed that of a single major feed item treated with parathion at the maximum use rate. Hence, the calculated maximum theoretical dietary burdens for livestock, assumes that livestock may be exposed to no more than one feed item containing maximum residues of parathion resulting from the maximum use rate of parathion and that the remainder of their diet will have zero residues of parathion. The calculated maximum theoretical dietary burdens for livestock are presented in the table below:

Calculation of maximum dietary burdens of livestock animals for parathion.

Feed Commodity	% Dry Matter ^a	% Diet ^a	Reassessed Tolerance (ppm) ^b	Dietary Contribution (ppm) ^c
Beef Cattle				
corn forage	40	40	8	8.0
all other feeds	--	60	--	0.0
TOTAL BURDEN		100		8.0
Dairy Cattle				
corn forage	40	50	8	10.0
all other feeds	--	50	--	0.0
TOTAL BURDEN		100		10.0
Poultry				
barley grain	N/A	75	5 ^d	3.8
all other feeds	N/A	25	--	0.0
TOTAL BURDEN		100		3.8
Swine				
barley grain	N/A	80	5 ^d	4.0
all other feeds	N/A	20	--	0.0
TOTAL BURDEN		100		4.0

^a Table 1 (August 1996).

^b Reassessed tolerance from Table C.

^c Contribution = [tolerance / % DM (if cattle)] X % diet).

^d Based on new barley grain field trial data (MRID 44602201) which are under review. The highest average field trial (HAFT) value for residues of parathion in/on barley grain is 4.22 ppm. The average field trial value for residues of parathion in/on barley grain is 0.9 ppm.

Parathion Residues of Concern in Milk and Meat: Based on the maximum theoretical dietary burdens for beef and dairy cattle (8 ppm and 10 ppm, respectively) and the available ruminant metabolism and magnitude of the residue data, there is no reasonable expectation of finite residues of parathion and paraoxon in milk, beef liver, beef muscle, beef kidney, and beef fat (40 CFR § 180.6(a)(3)). Therefore, no tolerances for residues of parathion in milk and meat are required.

Parathion Residues of Concern in Egg and Poultry: Based on the maximum theoretical dietary burden for poultry (3.8 ppm) and the available poultry metabolism and magnitude of the residue data, there is some uncertainty whether finite residues of parathion will be incurred in egg, poultry muscle, poultry fat, and poultry liver (40 CFR § 180.6(a)(2)); however, there is no reasonable expectation of finite residues of paraoxon in egg and poultry tissues (40 CFR § 180.6(a)(3)). Therefore, tolerances for residues of parathion should be established in eggs, poultry muscle, poultry fat, and poultry liver. Based on the available poultry magnitude of the residue data, the maximum residues of parathion resulting from the maximum theoretical dietary burden to poultry (3.8 ppm) are estimated at 0.6 ppb in eggs, 0.3 ppb in poultry muscle, 2 ppb in poultry fat, and 4 ppb in poultry liver. Tolerance levels should be set at the limit(s) of quantitation (LOQ) of the enforcement method(s). A tolerance level of 1 ppb or 0.001 ppm would be appropriate for egg

and 10 ppb or 0.01 ppm would be appropriate for poultry muscle, poultry fat, and poultry liver.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

Parathion is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Parathion is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

The registrant (Cheminova) has submitted confined rotation crop data (no MRID; ABC Laboratories Report 36837-3; cover letter from Jellinek, Swartz & Connolly, Inc. dated 11/12/91) which are under review. Pending acceptance of these data to satisfy guideline requirements, no additional confined rotational crop data are required to support the reregistration of parathion.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops:

The need for limited field rotational crop studies and appropriate plantback intervals will be determined once data from the confined rotational crop study have been reviewed.

TABLE A. FOOD/FEED USE SITES, MAXIMUM USE PATTERNS, and RESTRICTIONS SUPPORTED UNDER THE REREGISTRATION PROCESS FOR PARATHION (CASE 0155). Note: The conclusions listed in Table B regarding the reregistration eligibility of parathion food/feed uses are predicated on the use information summarized in this Table.

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class	Maximum Single Application Rate (ai)	Max. # Apps. ^a	Minimum Spray Volume ^b (gal/A)	Minimum Retreatment Interval (Days)	Pre- Harvest Interval (Days)	Use Restrictions ^c
LEGUME VEGETABLES GROUP							
Soybeans							
Broadcast application Aerial equipment	4 lb/gal EC ^d 6 lb/gal EC ^e 8 lb/gal EC ^f	0.75 lb/A	2	2	7	20	Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
CEREAL GRAINS GROUP							
Barley							
Broadcast application Aerial equipment	4 lb/gal EC ^d 6 lb/gal EC ^e 8 lb/gal EC ^f	0.75 lb/A	6	2	7	15	

Table A (Continued)

CROP GROUP		Maximum Single Application Rate (ai)	Max. # Apps. ^a	Minimum Spray Volume ^b (gal/A)	Minimum Retreatment Interval (Days)	Pre- Harvest Interval (Days)	Use Restrictions ^c
Crop Application Type Application Timing Application Equipment	Formulation Class						
Corn, field, pop, sweet							
Broadcast application Aerial equipment	4 lb/gal EC ^d 6 lb/gal EC ^e 8 lb/gal EC ^f	0.75 lb/A	6	2	7	12	
Sorghum, grain ^g							
Broadcast application Aerial equipment	4 lb/gal EC ^d 8 lb/gal EC ^f	1.0 lb/A	2	2	7	12-forage 28-grain 28-stover	
Wheat							
Broadcast application Aerial equipment	4 lb/gal EC ^d 6 lb/gal EC ^e 8 lb/gal EC ^f	0.50 lb/A	2	2	14	15	
NON-GRASS ANIMAL FEEDS GROUP							
Alfalfa (grown for forage and hay only)							
Broadcast application Aerial equipment	4 lb/gal EC ^d 6 lb/gal EC ^e 8 lb/gal EC ^f	0.50 lb/A	2 per cutting	2	7	15	

Table A (Continued)

CROP GROUP		Maximum Single Application Rate (ai)	Max. # Apps. ^a	Minimum Spray Volume ^b (gal/A)	Minimum Retreatment Interval (Days)	Pre- Harvest Interval (Days)	Use Restrictions ^c
Crop Application Type Application Timing Application Equipment	Formulation Class						
MISCELLANEOUS							
Canola (oilseed crop only)							
Broadcast application	4 lb/gal EC ^d	0.50 lb/A	2	2	7	28	
Aerial equipment	6 lb/gal EC ^e 8 lb/gal EC ^f						
Cotton							
Broadcast application	4 lb/gal EC ^d	1.0 lb/A	6	2	7	7	
Aerial equipment	6 lb/gal EC ^e 8 lb/gal EC ^f						
Sunflowers							
Broadcast application	4 lb/gal EC ^d	1.0 lb/A	3	2	5	30	
Aerial equipment	6 lb/gal EC ^e 8 lb/gal EC ^f						

^a Maximum number of applications at the maximum single application rate.

^b Diluent is water unless otherwise specified under restrictions.

^c All end-use product labels must include the following restrictions: Aerial applications only. Treated crops must be mechanically harvested; hand harvesting of treated crops is prohibited.

^d 4 lb ai/gal emulsifiable concentrate (EC) formulation; Cheminova PARATHION 4 EC; EPA Reg. No. 67760-37.

^e 6 lb ai/gal emulsifiable concentrate (EC) formulation; ETHYL-METHYL PARATHION 6-3EC; EPA Registration No. 67760-39. This is a multiple active ingredient (MAI) formulation containing 6 lb ai/gal of ethyl parathion in addition to 3 lb ai/gal of methyl parathion.

^f 8 lb ai/gal emulsifiable concentrate (EC) formulation; Cheminova PARATHION 8EC; EPA Reg. No. 67760-38.

^g The 6 lb ai/gal emulsifiable concentrate (EC) formulation, which is a multiple active ingredient (MAI) formulation containing 6 lb ai/gal of ethyl parathion in addition to 3 lb ai/gal of methyl parathion cannot be used on sorghum since the use of methyl parathion on sorghum is not being supported under reregistration.

Table B. Residue Chemistry Science Assessments for Reregistration of Parathion.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A	Yes ²	See Table A.
860.1300: Plant Metabolism	N/A	No	GS00155001 GS00155002 00160331 40751601 40810901 41228601 41343701 41414101 41715401 42672401
860.1300: Animal Metabolism	N/A	No	00057039 40288901 40288902 40623803 40784401 41397601 41398001 43107501 ³ 43196801 ³
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	00003724 00035332 00047726 00101098 00101100 00101118 00101122 00101127 GS00155004 42133601 42575701 ⁴ 42709101 43216201 ³ 43556001 ⁵
- Animal commodities	N/A	No ⁶	00088048 00101106 00101107 44133201 ⁷ 44547401 ⁶
860.1360: Multiresidue Methods	N/A	No	
860.1380: Storage Stability Data	N/A	No ⁸	00101166 42161201 42544701 42666701 43685601 ⁹ 44559601 ⁸ 44640501 ⁸
860.1500: Crop Field Trials			
<u>Legume Vegetables (Succulent or Dried) Group</u>			
- Soybeans	0.1 [§180.121(a)]	No ¹⁰	00101100 41344207

Table B (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
<u>Foliage of Legume Vegetables Group</u>			
- Soybeans forage and hay	1 (hay) [§180.121(a)]	No ¹¹	00101100 41344207
<u>Cereal Grains Group</u>			
- Barley	1 [§180.121(a)]	No ¹²	44602201 ¹²
- Corn	1 [§180.121(a)]	No ¹³	41717707
- Sorghum	0.1 (N) [§180.121(a)]	No ¹⁴	00101098 00101226 41412504 43546601 ¹⁵
- Wheat	1 [§180.121(a)]	No ¹⁶	43239501 ³ 43511302 ⁵ 44590201 ¹⁶
<u>Forage Fodder and Straw of Cereal Grains</u>			
- Barley hay and straw	None	No ¹²	44602201 ¹²
- Corn forage and stover	1 (forage) [§180.121(a)]	No ¹⁷	41717707
- Sorghum forage and stover	3 [§180.121(a)]	No ¹⁴	00058046 00061199 00101098 00101213 00101226 43546601 ¹⁵
- Wheat forage, hay and straw	None	Yes ¹⁶	00101114 43239501 ³ 43511302 ⁵
<u>Non-grass Animal Feeds</u>			
- Alfalfa (fresh)	1.25 [§180.121(a)]	Yes ¹⁸	00035332 00047726 00061199 00101111 00101118 00101119
- Alfalfa hay	5 [§180.121(a)]	Yes ¹⁸	00101121 00101124
<u>Miscellaneous Commodities</u>			

Table B (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Aspirated grain fractions	None	No ¹⁹	43511301 ⁵ 44591401 ²⁰ 44590201 ¹⁹ 44591301 ¹⁹
- Cottonseed	0.75 [§180.121(a)]	No ²¹	00101122 00101226 41344210 44594901 ²¹
- Canola	0.2 (rape seed) [§180.121(a)]	No	00003724 42709102 43624201 ⁵
- Sunflower seed	0.2 [§180.121(a)]	No	41596109 42077801
860.1520: Processed Food/Feed			
- Barley	None	No ²²	
- Corn (field)	None	No ²³	41596102
- Cottonseed	None	No	41717703
- Canola	None	No	42709103
- Sorghum	None	No	41717705
- Soybeans	None	Yes ²⁴	
- Sunflower seed	None	No	44590601 ²⁰
- Wheat	None	No ²⁵	43511301 ⁵
860.1480: Meat, Milk, Poultry, and Eggs	None	No ²⁶	00088048 00101104 00101105 00101106 44527301 ²⁷ 44527302 ²⁷
860.1400: Water Fish and Irrigated Crops	None	N/A	
860.1460: Food Handling	None	N/A	

Table B (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1850: Confined Rotational Crops	N/A	No ²⁸	Letter dated 11/12/91 ²⁸
860.1900: Field Rotational Crops	None	N/A ²⁸	

1. **Bolded** references were reviewed in the Residue Chemistry Chapter of the Parathion Reregistration Standard dated 4/8/85, and *italicized* references were reviewed in the Residue Chemistry Chapter of the Parathion Reregistration Standard Update dated 8/17/93. All other references were reviewed as noted.
2. Registrants must amend all end-use product labels for the EC formulations of parathion, as necessary, to conform to the Agency's prescribed food/feed use sites, maximum use patterns, and restrictions specified in Table A. [Note: Since, the use of methyl parathion on sorghum is not being supported under reregistration, all end-use product labels for the EC formulations of parathion containing 3 lb/gal of methyl parathion and 6 lb/gal of ethyl parathion must be amended to delete uses on sorghum.]
3. CB Nos. 13359, 13651, 14024; DP Barcodes D200095, D202635, D205594; S. Hummel; 12/20/94.
4. CBRS No. 11230, DP Barcode D186341, L. Cheng, 5/5/93.
5. DP Barcodes D212528, D213012, and D215507; B. Cropp-Kohlligian; 5/27/98.
6. The registrant (Cheminova) has submitted new data concerning an Independent Laboratory Validation (ILV) of the analytical methodology (MRID 44547401) for analysis of residues of parathion, paraoxon, and 4-acetamidoparaoxon in kidney and milk which are under review. Pending acceptance of these data to satisfy guideline requirements, no additional plant and animal residue analytical method data are required from the registrant to support the reregistration of parathion.
7. CBRS No. 17624, DP Barcode D230692, B. Cropp-Kohlligian, 3/12/97.
8. The registrant (Cheminova) has submitted new storage stability data on field corn grain and the processed commodities of field corn grain (MRID 44559601) and test sample storage conditions/intervals data (MRID 44640501) to support the reregistration of the EC formulation of parathion which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the tolerance reassessment recommendations made herein or dietary exposure estimates used in the dietary risk assessment for parathion. No additional storage stability data are required to support the reregistration of parathion.
9. CB No. 15803, DP Barcode D216966, B. Cropp-Kohlligian, 9/24/97.
10. The available data are adequate and indicate that the currently established tolerance for residues of parathion in/on soybeans should be decreased from 0.1 ppm to 0.05 ppm.
11. Provided the registrants amend all end-use product labels to prohibit the feeding or grazing of treated soybean forage and hay to livestock, no soybean forage and hay residue chemistry data are required to support the reregistration of parathion. No tolerances for residues of parathion in/on soybean forage and soybean hay are needed.

Table B (continued).

12. The registrant (Cheminova) has submitted new barley grain, hay, and straw magnitude of the residue data (MRID 44602201) to support the use of the EC formulation of parathion on barley which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessment for parathion; however, these data do indicate that it may be appropriate to increase the currently established tolerance for residues of parathion in/on barley grain from 1 ppm to 5 ppm and establish tolerances for residues of parathion in/on barley hay and barley straw at 5 ppm and 13 ppm, respectively. Pending acceptance of the subject barley field trial data to support the use of the EC formulation of parathion on barley, no additional barley field trial data are required to support the reregistration of parathion.
13. The available data are adequate and support establishing separate tolerances for residues of parathion in/on field corn grain and pop corn grain at 0.1 ppm and in/on sweet corn (K+CWHR) at 0.05 ppm.
14. The available data are adequate and indicate that: (i) the established tolerance for residues of parathion in/on sorghum grain should be increased from 0.1 ppm to 2 ppm, (ii) the established tolerance for residues of parathion in/on sorghum forage should be decreased from 3 ppm to 2 ppm, and (iii) the established tolerance for residues of parathion in/on fodder (stover) should be increased from 3 ppm to 13 ppm.
15. DP Barcode D216095, B. Cropp-Kohlligian, 5/21/98.
16. The available wheat grain, wheat forage and wheat straw data are adequate and indicate that the currently established tolerance for residues of parathion in/on wheat grain (1 ppm) is appropriate and that tolerances for residues of parathion should be established in wheat forage and wheat straw at 1 ppm and 5 ppm, respectively. The registrant (Cheminova) has submitted new wheat grain/aspirated grain fractions (AGF) magnitude of the residue data (MRID 44590201) to support the use of the EC formulation of parathion on wheat which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the tolerance reassessment recommendations made herein or dietary exposure estimates used in the dietary risk assessment for parathion.

No wheat hay data reflecting the maximum use rate of parathion in/on wheat are available. Additional data are required depicting parathion residues of concern in/on wheat hay harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.50 lb ai/A/application with a 14-day RTI. [Note: It is inappropriate to translate available barley hay data to wheat hay since the available barley hay data reflect a significantly higher use rate of parathion than that which is being support for the use of parathion on wheat.] However, the Agency will limit the number of field trials needed to three bridging wheat field trials, one each in Regions 5, 7, and 8 conducted at the 1x rate in which all RACs of wheat are collected. [Note: The registrant (Cheminova) has not committed to generated these data.]
17. The available corn forage data are adequate and support increasing the currently established tolerance for residues of parathion in/on corn forage from 1 ppm to 8 ppm. Separate tolerances should be established for residues of parathion in/on sweet corn forage and field corn forage.

The available corn fodder data are adequate to support the establishment of separate tolerances for residues of parathion in/on field corn stover, pop corn stover, and sweet corn stover at 20 ppm.

Table B (continued).

18. There are no alfalfa field trial data reflecting the maximum use rate of parathion on alfalfa using the currently registered EC formulation. Data are required depicting parathion residues of concern in/on alfalfa forage and hay reflecting the maximum use rate of the EC formulation of parathion on alfalfa. The registrant should refer to OPPTS GLN 860.1500 for information on location and number of field trials required. Since it is unlikely that the currently established tolerances for residues of parathion in/on alfalfa forage and alfalfa hay are adequate, the required data are considered critical to tolerance reassessment. [Note: The registrant (Cheminova) has committed to generate the subject data.]

19. The registrant (Cheminova) has submitted new data depicting parathion residues of concern in the aspirated grain fractions (AGF) derived from sorghum grain (MRID 44591301) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the tolerance reassessment recommendations made herein or dietary exposure estimates used in the dietary risk assessment for parathion. Pending acceptance of these data to support the use of the EC formulation of parathion on grain sorghum, no additional AGF magnitude of the residue data are required to support the reregistration of parathion.

Adequate wheat grain dust data (MRID 43511301) are available indicating that residues of parathion in/on wheat grain dust are 4.5x higher than in/on wheat grain. Based on the HAFT value for residues of parathion in/on wheat grain (0.52 ppm) and the concentration factor for the AGF of wheat (4.5x), a tolerance of 3 ppm would be appropriate. Note: The registrant (Cheminova) has submitted new wheat grain/aspirated grain fractions (AGF) magnitude of the residue data (MRID 44590201) to support the use of the EC formulation of parathion on wheat which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the tolerance reassessment recommendations made herein or dietary exposure estimates used in the dietary risk assessment for parathion.

20. DP Barcodes D247485 and D247511, B. Cropp-Kohlligian, 1/28/99.

21. The registrant (Cheminova) has submitted new cottonseed and cotton gin trash magnitude of the residue data (MRID 44594901) to support the use of the EC formulation of parathion on cotton which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessment for parathion; however, these data do indicate that it may be appropriate to increase the currently established tolerance for residues of parathion in/on cottonseed from 0.75 ppm to 2 ppm. Also, based on the HAFT value for residues of parathion in/on cottonseed (1.65 ppm) and the average concentration factor for cotton gin byproducts (21x), a tolerance for residues of parathion in cotton gin trash should be established at 35 ppm. Pending acceptance of the subject data to support the use of the EC formulation of parathion on cotton, no additional cottonseed and cotton gin trash magnitude of the residue data are required to support the reregistration of parathion.

22. Processing data from wheat grain will be translated to barley grain processed commodities. The registrant (Cheminova) has submitted new barley grain magnitude of the residue data (MRID 44602201) to support the use of the EC formulation of parathion on barley which are under review. A preliminary evaluation of these data indicates that it may be appropriate to increase the currently established tolerance for residues of parathion in/on barley grain from 1 ppm to 5 ppm. Based on the HAFT value for residues of parathion in/on barley grain (4.3 ppm) and the concentration factor observed for wheat bran (4.6x), it may be appropriate to establish a tolerance for residues of parathion in barley bran at 20 ppm.

Table B (continued).

23. The available field corn grain processing data are adequate. Based on the HAFT value for residues of parathion in/on field corn grain (0.0877 ppm) and the observed concentration factor in refined corn oil (3x), it may be appropriate to establish a tolerance for residues of parathion in refined corn oil at 0.3 ppm.
24. Data are required depicting the potential for concentration of parathion residues of concern in soybean hulls, meal, and oil processed from seeds bearing detectable parathion residues. If no detectable residues of parathion are found in/on soybeans harvested from plants treated at a 5x exaggerated rate, a processing study will not be required.
25. The available data are adequate and support the establishment of a tolerance for residues of parathion in wheat bran. Based on the HAFT value for residues of parathion in/on wheat grain (0.52 ppm) and the observed concentration factor for wheat bran (4.6x), a tolerance of 3 ppm for residues of parathion in wheat bran may be appropriate.
26. The available ruminant and poultry feeding studies are deemed adequate to support the reregistration of parathion. No additional meat, milk, poultry, and egg magnitude of the residue data are required.

For milk and meat: Based on the maximum theoretical dietary burdens for beef and dairy cattle (8 ppm and 10 ppm, respectively) and the available ruminant metabolism and magnitude of the residue data there is no reasonable expectation of finite residues of parathion and paraoxon in milk, beef liver, beef muscle, beef kidney, and beef fat (40 CFR § 180.6(a)(3)). Therefore, no tolerances for residues of parathion in milk and meat are required.

For poultry and egg: Based on the maximum theoretical dietary burden for poultry (3.8 ppm) and the available poultry metabolism and magnitude of the residue data there is some uncertainty whether finite residues of parathion will be incurred in egg, poultry muscle, poultry fat, and poultry liver (0 CFR § 180.6(a)(2)); however, there is no reasonable expectation of finite residues of paraoxon in egg and poultry tissues (40 CFR § 180.6(a)(3)). Therefore, tolerances for residues of parathion should be established in eggs, poultry muscle, poultry fat, and poultry liver. Based on the available poultry magnitude of the residue data, the maximum residues of parathion resulting from the maximum theoretical dietary burden to poultry (3.8 ppm) are estimated at 0.6 ppb in eggs, 0.3 ppb in poultry muscle, 2 ppb in poultry fat, and 4 ppb in poultry liver. Tolerance levels should be set at the limit(s) of quantitation (LOQ) of the enforcement method(s). A tolerance level of 1 ppb or 0.001 ppm would be appropriate for egg and 10 ppb or 0.01 ppm would be appropriate for poultry muscle, poultry fat, and poultry liver.

27. DP Barcode D248095; B. Cropp-Kohlligian; 8/13/99.
28. A confined rotational crop study (no MRID; ABC Laboratories Report 36837-3; cover letter from Jellinek, Swartz & Connolly, Inc. dated 11/12/91) has been submitted and is under review. Pending acceptance of these data to satisfy OPPTS GLN 860.1850 data requirements, no additional confined rotational crop data are required to support the reregistration of parathion. The need for limited field rotational crop data to satisfy OPPTS GLN 860.1900 requirements and/or plantback restrictions will be determined once the confined rotational crop study has been reviewed.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of parathion are currently expressed in terms of parathion or its methyl homolog (methyl parathion) [40 CFR §180.121 (a) and §180.319]. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohligian dated 5/21/98) has determined that the tolerance expression for parathion residues of concern in/on plant commodities may be based on residues of parathion only.

Tolerances for parathion should be moved from 40 CFR §180.121(a) and listed under a separate 40 CFR §180.XXX (a) section. Under the new listing, tolerances should only be established for RACs and, if necessary, processed commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat, in accordance with an agreement limiting the use of parathion to these crops. All other currently established tolerances for residues of parathion listed under 40 CFR §180.121 (a) and §180.319 should be revoked.

The tolerance definition for parathion residues should also be changed to read as follows:

Tolerances are established for the residues of parathion [*O,O*-diethyl-*O-p*-nitrophenyl thiophosphate] in/on the following raw agricultural commodities:

A summary of the parathion tolerance reassessment for commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat only are presented in Table C. Table C also includes modifications in commodity definitions where needed.

Tolerances Listed Under 40 CFR §180.121 (a):

Tolerances should only be established for RACs and, if necessary, processed commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat, in accordance with an agreement limiting the use of parathion to these crops. All other currently established tolerances for residues of parathion listed under 40 CFR §180.121 (a) should be revoked.

In support of the reregistration of parathion, the registrant (Cheminova) has submitted the following residue chemistry data, which are under review: (i) barley grain, hay, and straw field trial data (MRID 44602201), (ii) magnitude of the residue data on aspirated grain fractions (AGF) derived from wheat grain (MRID 44590201) and sorghum grain (MRID 44591301), and (iii) cotton gin trash magnitude of the residue data (MRID 44594901).

Pending acceptance of the residue chemistry data detailed above to fulfill guideline requirements and provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, maximum use patterns, and restrictions as specified in Table A, sufficient data are available to reassess tolerances for residues of parathion in/on barley grain, field corn grain, pop corn grain, sweet corn (K+CWHR), field corn forage, sweet corn forage, undelinted cottonseed, canola seed, grain sorghum grain, grain sorghum forage, grain sorghum stover, soybean seed, sunflower seed and wheat grain. The tolerance for residues of parathion in/on soybean hay is not being supported and should be revoked.

Data indicate that the currently established tolerance levels for residues of parathion in/on canola seed (0.2

ppm), sunflower seed (0.2 ppm), and wheat grain (1 ppm) are appropriate. Data indicate that the currently established tolerance levels for residues of parathion should be decreased in/on field corn grain (from 1 ppm to 0.1 ppm), pop corn grain (from 1 ppm to 0.1 ppm), sweet corn (K+CWHR; from 1 ppm to 0.05 ppm), grain sorghum forage (from 3 ppm to 2 ppm), and soybean seed (from 0.1 ppm to 0.05 ppm). Data indicate that the currently established tolerance levels for residues of parathion should be increased on barley grain (from 1 ppm to 5 ppm), field corn forage (from 1 ppm to 8 ppm), sweet corn forage (from 1 ppm to 8 ppm), cottonseed (from 0.75 ppm to 2 ppm), grain sorghum grain (from 0.1 ppm to 2 ppm), and grain sorghum stover (from 3 ppm to 13 ppm).

Additional residue data deemed critical to tolerance reassessment are required before existing tolerances can be reassessed on alfalfa forage and alfalfa hay. It is unlikely that the currently established tolerances for residues of parathion in/on these commodities are adequate.

Tolerances Listed Under 40 CFR §180.319:

As there is no registered use for parathion on rye, the tolerance for parathion residues in/on rye should be revoked.

Tolerances Needed Under 40 CFR §180.XXX:

New tolerances are needed for residues of parathion in/on the following RACs of plants: aspirated grain fractions, barley hay and straw, corn stover, cotton gin byproducts, and wheat forage, hay and straw. Pending acceptance of the residue chemistry data detailed above to fulfill guideline requirements and provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, maximum use patterns, and restrictions as specified in Table A, sufficient data are available to determine appropriate tolerance levels for residues of parathion in/on aspirated grain fractions (3 ppm), barley hay (5 ppm), barley straw (13 ppm), corn stover (20 ppm), cotton gin by products (35 ppm), wheat forage (1 ppm), and wheat straw (5 ppm).

Additional wheat hay magnitude of the residue data are required. An appropriate tolerance for residues of parathion in/on wheat hay cannot be determined without the required data. It is uncertain if the currently established tolerance for residues of parathion in/on wheat (1 ppm) is adequate to cover residues of parathion in/on wheat hay.

New tolerances are needed for residues of parathion in/on the following processed food/feed commodities: barley bran, refined corn oil, and wheat bran. Pending acceptance of the residue chemistry data detailed above to fulfill guideline requirements and provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, maximum use patterns, and restrictions as specified in Table A, sufficient data are available to determine appropriate tolerance levels for residues of parathion in/on barley bran (20 ppm), refined corn oil (0.3 ppm), and wheat bran (3 ppm).

Soybean seed processing data remain outstanding. The need for new tolerances for residues of parathion in soybean hulls, meal, and oil cannot be determined without the required data.

New tolerance are needed for residues of parathion in egg, poultry liver, poultry muscle, and poultry fat. Sufficient data are available to determine appropriate tolerance levels for residues of parathion in egg (0.001 ppm), poultry liver (0.01 ppm), poultry muscle (0.01 ppm), and poultry fat (0.01 ppm).

Table C. Tolerance Reassessment Summary for Parathion. [NOTE: Tolerances should only be established for RACs and, if necessary, processed commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat, in accordance with an agreement limiting the use of parathion to these crops. All other currently established tolerances for residues of parathion listed under 40 CFR §180.121 (a) and §180.319 should be revoked.]

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Correct Commodity Definition Comments
Tolerances listed under 40 CFR §180.121 (a):			
Alfalfa, (fresh)	1.25	TBD ^a	<i>Alfalfa, forage</i> It is unlikely that the currently established tolerance in/on alfalfa fresh is adequate. Hence, data deemed critical to tolerance reassessment remain outstanding.
Alfalfa, (hay)	5	TBD	<i>Alfalfa, hay</i> It is unlikely that the currently established tolerance in/on alfalfa hay is adequate. Hence, data deemed critical to tolerance reassessment remains outstanding.
Barley	1	5	<i>Barley, grain</i> New barley grain, hay, and straw field trial data (MRID 44602201) are under review. A preliminary evaluation of these data indicates that it may be appropriate to increase the currently established tolerance in/on barley grain from 1 ppm to 5 ppm.
Corn	1	0.1	<i>Corn, field, grain</i> <i>Corn, pop, grain</i> The available residue data support decreasing the tolerance from 1 ppm to 0.1 ppm.
		0.05	<i>Corn, sweet: K+CWHR</i> The available residue data support decreasing the tolerance from 1 ppm to 0.05 ppm.
Corn, forage	1	8	<i>Corn, field, forage</i> <i>Corn, sweet, forage</i> The available residue data support increasing the tolerance from 1 ppm to 8 ppm.
Cottonseed	0.75	2	<i>Cotton, undelinted seed</i> New cottonseed and cotton gin trash magnitude of the residue data (MRID 44594901) are under review. A preliminary evaluation of these data indicates that it may be appropriate to increase the currently established tolerance in/on cottonseed from 0.75 ppm to 2 ppm.
Rape seed	0.2	0.2	<i>Canola, seed</i>
Sorghum	0.1	2	<i>Sorghum, grain, grain</i> The available residue data support increasing the tolerance from 0.1 ppm to 2 ppm.

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Correct Commodity Definition Comments
Sorghum fodder	3	13	<i>Sorghum, grain, stover</i> The available residue data support increasing the tolerance from 3 ppm to 13 ppm.
Sorghum forage	3	2	<i>Sorghum, grain, forage</i> The available residue data support decreasing the tolerance from 3 ppm to 2 ppm.
Soybean	0.1	0.05	<i>Soybean, seed</i> The available residue data support decreasing the tolerance from 0.1 ppm to 0.05 ppm.
Soybean hay	1.0	Revoke	Not supported under reregistration.
Sunflower seed	0.2	0.2	<i>Sunflower, seed</i>
Wheat	1	1	<i>Wheat, grain</i>
Tolerances listed under 40 CFR §180.319:			
Rye	0.5	Revoke	Temporary tolerance no longer in effect. Not supported under reregistration.
Tolerances needed under 40 CFR §180.XXX (a)			
Aspirated grain fractions	None	3	Based on the HAFT value for residues of parathion in/on wheat grain (0.52 ppm) and the observed concentration factor for AGF derived from wheat grain (4.5x), a tolerance of 3 ppm would be appropriate.
Barley, bran	None	20	New barley grain data (MRID 44602201) are under review. Based on the HAFT value in/on barley grain (4.3 ppm) and translating the observed concentration factor for wheat bran (4.6x), a tolerance of 20 ppm would be appropriate.
Barley, hay	None	5	New barley grain, hay, and straw field trial data (MRID 44602201) are under review. A preliminary evaluation of these data indicates that it may be appropriate to establish tolerances for residues of parathion in/on barley hay and barley straw at 5 ppm and 13 ppm, respectively.
Barley, straw	None	13	
Corn, oil, refined	None	0.3	Based on the HAFT value in/on field corn grain (0.0877 ppm) and the observed concentration factor for refined corn oil (3x), a tolerance of 0.3 ppm would be appropriate.
Corn, stover	None	20	<i>Corn, field, stover</i> <i>Corn, pop, stover</i> <i>Corn, sweet stover</i> Tolerances are based upon available residue data on corn fodder.

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	<i>Correct Commodity Definition</i> Comments
Cotton gin byproducts	None	35	New cottonseed and cotton gin trash magnitude of the residue data (MRID 44594901) are under review. Based on the HAFT value for residues of parathion in/on cottonseed (1.65 ppm) and the observed concentration factor for cotton gin trash (21x), a tolerance of 35 ppm would be appropriate.
Egg	None	0.001	
Poultry liver Poultry muscle Poultry fat	None	0.01	
Wheat, forage	None	1	
Wheat, bran	None	3	Based on the HAFT value for residues of parathion in/on wheat grain (0.52 ppm) and the observed concentration factor for wheat bran (4.6x), a tolerance of 3 ppm would be appropriate.
Wheat, hay	None	TBD	
Wheat, straw	None	5	

^a TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for parathion residues in/on various fruit and vegetable commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex MRLs for parathion are currently expressed in terms of the parent. The U.S. tolerance definition will be compatible with Codex. A comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table D.

Table D. Codex MRLs for parathion and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL ¹ (mg/kg)	Step		
Apple	0.05	6	None	Not registered for this use in the U.S.
Apricot	1	CXL	None	Not registered for this use in the U.S.
Cotton seed	1	CXL	2	
Leek	0.05	CXL	None	Not registered for this use in the U.S.
Lemon	0.5	CXL	None	Not registered for this use in the U.S.
Maize	0.1	CXL	0.1	U.S. commodity defined as "Corn, field, grain".
Mandarin	0.5	CXL	None	Not registered for this use in the U.S.
Olive oil, Virgin	2	CXL	None	Not registered for this use in the U.S.
Olives	0.5	CXL	None	Not registered for this use in the U.S.
Oranges, Sweet, Sour	0.5	CXL	None	Not registered for this use in the U.S.
Peach	1	CXL	None	Not registered for this use in the U.S.
Potato	0.5	CXL	None	Not registered for this use in the U.S.
Sorghum	5	CXL	2	U.S. commodity defined as "Sorghum, grain, grain".
Soya bean (dry)	0.05	CXL	0.05	U.S. commodity defined as "soybean, seed".
Sunflower seed	0.05	CXL	0.2	

^a An asterisk (*) signifies that the MRL was established at or about the limit of detection.